

Reporting Systems

Harmful Medication Errors Involving Unfractionated and Low-Molecular-Weight Heparin in Three Patient Safety Reporting Programs

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Since the release of the Institute of Medicine's report *To Err Is Human*¹ in 1999, the competing interests of health care organizations, professional responsibilities, and the potential impact on liability exposure have spurred the use of patient safety reporting programs to identify actual and potential failures. The external reporting of medical errors and adverse events has become an important health policy topic in the United States and in other industrialized countries.²⁻⁷ Patient safety reporting programs enable us to learn from the errors of others in the pursuit of systems-level improvements that can prevent future errors.⁴ By September 2005, 24 states in the United States had passed legislation to create or improve reporting systems for hospital-based adverse events.⁸

Lucian Leape has summarized the characteristics of successful reporting systems: a nonpunitive approach, confidentiality, independence, expert analysis, timeliness, a systems-level orientation, and responsiveness.⁴ The variation in reporting programs presents both a challenge and an opportunity as the U.S. Agency for Healthcare Research and Quality (AHRQ) establishes the National Network of Patient Safety Databases under the Patient Safety and Quality Improvement Act of 2005. This network will permit aggregating data from multiple reporting programs, which may enable identification of otherwise unrecognized hazards and provide more compelling evidence for the significance of known problems.⁹ The law assumes that there will be value in aggregating data from many diverse systems using common formats, a proposition that the study reported in this article attempted to explore.

Anticoagulants are among the most frequently cited product classes involved in harmful medication errors.¹⁰⁻¹³ They are considered "high-alert" medications by the Institute for Safe Medication Practices (ISMP) because they bear a heightened risk of significant harm, including death, when used in error.¹⁴ In 2007 The Joint Commission established a National Patient Safety Goal, now known as NPSG.03.05.01, "Reduce the likelihood of patient harm associated with the use of anticoagulant

Article-at-a-Glance

Background: External reporting of medical errors and adverse events enables learning from the errors of others in the pursuit of systems-level improvements that can prevent future errors. It is logical to presume that medication errors involving the use of anticoagulants, among the most frequently cited product classes involved in harmful medication errors, would be captured in a variety of patient safety reporting programs.

Methods: Data on reported errors involving the anticoagulant heparin were reviewed, compared, and aggregated from the databases of three large patient safety reporting programs—MEDMARX®, the Pennsylvania Patient Safety Authority's Patient Safety Reporting System, and the University Health System Consortium, together representing more than 1,000 reporting organizations for 2005.

Results: Approximately 300,000 medication errors and near misses were reported to the programs, and 10,359—a mean of 3.6% (range, 3.1%–5.5%)—involved heparin products. The proportion of heparin-related reports that involved patient harm ranged from 1.4% to 4.9%. The phase of the medication use process cited most frequently in harmful events was the administration phase (56% of errors leading to harm), followed by the prescribing phase (19% of errors leading to harm).

Discussion: This study represents the first attempt by these three large reporting systems to combine data on a single clinical process. The consistent patterns evident in the reports, such as the percentage of all medication errors that involved heparin, suggests that reporting programs, at least for common events such as medication errors, may reach a point of diminishing returns in which aggregating more reports of a certain type yields no additional insight once a large volume of similar events is captured and analyzed.

therapy.”¹⁵ In 2008, it issued a Sentinel Event Alert on this same topic.¹⁶ The Institute for Healthcare Improvement (IHI) 5 Million Lives From Harm campaign also identifies anticoagulants as a category of medications in which to focus error-prevention efforts.¹⁷ Because of anticoagulants’ widespread clinical use, it is logical to presume that medication errors involving their use would be captured in a variety of patient safety reporting programs. Yet, aggregating data on medication errors due to anticoagulants from multiple patient safety reporting programs can only suggest the frequency of error reports involving these drugs, recognizing that counting error reports underestimates the true frequency because of underreporting and other biases inherent in this type of data. The purpose of this article was to aggregate data on reported errors involving the anticoagulant heparin from three large patient safety reporting programs and to examine the similarities and differences in the data obtained from each program. We also extracted valuable “stories” from the descriptions of selected harmful errors from each program to determine more specifically what went wrong in these events and possible reasons why harm occurred to patients receiving heparin.

The Three Reporting Programs

MEDMARX®*

MEDMARX is a commercially available, subscription-based, Internet-accessible, anonymous, interactive medication error and adverse drug reaction-reporting program used by hospitals and health systems in quality improvement efforts associated with safe medication use. Since the launch of MEDMARX in 1998, more than 2 million adverse drug events from more than 1,000 health care organizations have been collected. MEDMARX data have been summarized, and findings have been presented by the United States Pharmacopeia (USP) through annual reports, case presentations, publications, and other dissemination activities.

PENNSYLVANIA PATIENT SAFETY AUTHORITY PATIENT SAFETY REPORTING SYSTEM

The Pennsylvania Patient Safety Authority Patient Safety Reporting System (PA-PSRS) is a confidential, statewide, Internet-based, mandatory patient safety reporting system, which includes medication errors and adverse drug reactions for hospitals, ambulatory surgical facilities, birthing centers, and some abortion facilities in Pennsylvania, the only state to require reporting of both harmful and nonharmful events and

near misses.¹⁸ Through February 2010, more than 1.13 million reports have been submitted since PA-PSRS was implemented in June 2004. Reports are analyzed by clinicians at the ECRI Institute and ISMP and are tabulated for trending. In turn, the Pennsylvania PSA publishes the quarterly *Pennsylvania Patient Safety Advisory*, which addresses high-volume issues, emerging trends, and unusual adverse events. Facilities use the reports and the *Advisory* for internal quality improvement and patient safety activities.

UNIVERSITY HEALTH SYSTEM CONSORTIUM

An alliance of 102 academic medical centers and more than 190 affiliated teaching hospitals, the University Health System Consortium (UHC) represents approximately 90% of nonprofit academic medical centers in the United States. UHC offers its members specific programs and services to improve clinical, operational, and patient safety performance. One such program is the UHC Patient Safety Net® (PSN), a Web-accessible, real-time patient safety reporting tool that includes medication errors and adverse drug reactions that was developed in 2002 using secure transfer protocols and complete transaction auditing. Currently, 75 organizations are participating, and the system has accumulated more than 1.3 million event reports. The PSN software and taxonomy served as the basis for PA-PSRS, and so the two have many similarities. All three programs contain reporting of near misses.

Methods

Institution Review Board (IRB) approval was not sought because all information analyzed contained no identifying information on patients.

Representatives from the three reporting programs (MEDMARX, PA-PSRS, and PSN), representing more than 1,000 reporting institutions, formed a research team in November 2006 to compare medication errors involving heparin products reported in their respective programs during 2005. All reports involving both unfractionated and low-molecular-weight heparin products were tabulated and reviewed. Common data fields among the three patient safety reporting programs were identified and included in this study. These fields were as follows: the anticoagulant product involved in the error, the severity of medication error, where the error occurred within an acute care setting, and the node of the error.

QUERY OF DATABASES

Generic and trade names for each of the heparin and low-molecular-weight products were queried from the databases in

* A United States Pharmacopeia (USP) program at the time of the study, MEDMARX has been owned and operated by Quantros, Inc., since December 2008.

Table 1. Text Strings Used to Search Database for Heparin and Low-Molecular-Weight Heparin*

"hepar" "loveno" "enoxa" "fragm" "dalt" "tinza" "innoh"

* Text strings are displayed in official database query language. For example, submitting a query that includes a wildcard character (for example, "hepar") would capture any drug containing those letters.

each program to obtain reported medication errors. The MEDMARX database was queried using Crystal Reports (Crystal Decisions, Inc., San Jose, California), Version 9. Researchers identified reported medication errors in the MEDMARX database that met the pre-established inclusion criteria (described on page 196). SQL Server 2005 (Microsoft, Redmond, Washington) was used to identify the common data fields in the PA-PSRS program. The UHC PSN database was queried by identifying medication errors that met the pre-established criteria by retrieving data using Microsoft Access®. Database functions of grouping and counting unique-event identifiers (IDs) provided the number, and related detail, of the medication errors that were used for the comparative analysis.

FOCUS ON HEPARIN REPORTS

This project focused on medication errors occurring in the acute care environment involving heparin products, including unfractionated heparin and low-molecular-weight heparin (for example, enoxaparin) products. In this article, we refer to all these products as *heparin*. All relevant reports submitted with the event date field (date of the event, not date of submission) that occurred in calendar year 2005 were included. We identified heparin reports by searching for the text strings listed in Table 1 (above) in the following fields: event narrative, recommendations to prevent recurrence (free-text), medication prescribed, and medication administered. Reports involving heparin flush were excluded.

SEVERITY

The severity for each medication error was determined using the nationally recognized taxonomy of the National Coordinating Council for Medication Error Reporting and Prevention (NCC MERP) *Index for Categorizing Medication Errors*.¹⁹ Each reporting program uses this index for classification, which has demonstrated good interrater reliability, with a Kappa value of $K = 0.62$.²⁰

ERROR DESCRIPTIONS

Error descriptions for each reported error that caused harm

were reviewed and categorized into nodes (prescribing, transcribing, dispensing, monitoring, and administration) whenever possible.

Results

FREQUENCY AND SEVERITY OF REPORTED ERRORS AND NEAR MISSES

Across the three programs, reports involving heparin (10,359) accounted for 3.6% of all medication-error (events that reached the patient) and "near-miss" (events that did not reach the patient) reports (214,276). The percentages of errors involving heparin across the three programs ranged from 3.1% to 5.5%. Table 2 (page 198) presents the distribution by each reporting program. Heparin-related reports involving patient harm—defined as those in Categories E through I using the NCC MERP Index—accounted for 2.7% of all heparin-related reports and 0.1% of all medication-error reports. The proportion of heparin-related reports that involved patient harm ranged from 1.4% to 4.9%.

NODES OF THE MEDICATION USE PROCESS

Prescribing, transcribing, dispensing, administering, and monitoring were identified as the "nodes" in the medication use process in which errors with heparin originated for each report. Among heparin-related reports involving patient harm, the administration node was cited by reporting hospitals in 56% of reported errors, followed by prescribing at 19%, transcribing at 12%, dispensing at 8%, and monitoring at 6%. Table 3 (page 198) displays the number of reports citing each node for each of the three programs. The most commonly cited nodes of origination were consistent across the three reporting programs, with each program independently citing administration and prescribing as the two most prevalent nodes of origination. It should be noted that the PSN and PA-PSRS programs ask reporters to list *all* applicable nodes, which would result in multiple selections for each report, while the MEDMARX programs asks reporters to select only one option.

CARE AREAS INVOLVED IN MEDICATION ERRORS

Each reporting program used different terms to categorize the areas where errors occurred, complicating the aggregation of this information. The care areas cited most frequently in heparin-related reports were general medicine with 4,094 reports (37% of total), pharmacy with 1,514 reports (14% of total), surgical units with 1,344 reports (12% of total), and the emergency department with 541 reports (5% of total). In the analysts' experience, reporters often confuse the care area in

Table 2. Total Number of Medication Errors and Near Misses and Those Involving Heparin and Low-Molecular-Weight Heparin According to Program, 2005*

	MEDMARX	PA-PSRS	PSN	Total
All Medication Errors and Near Misses	214,276	42,773	27,334	284,383
Heparin Errors and Near Misses [†]	6,725	2,367	1,267	10,359
Harm from Heparin (E Through I) [‡]	179	34	62	275
Heparin Reports as Percent of All Reports [†]	3.1%	5.5%	4.6%	3.6%
Harmful Errors from Heparin as Percent of All Reports [†]	0.08%	0.08%	0.23%	0.1%
Percent of Heparin Reports Resulting in Harm [‡]	2.7%	1.4%	4.9%	2.7%

* PA-PSRS, Pennsylvania Patient Safety Reporting System; PSN, Patient Safety Net (United Health System Consortium).

[†] Includes unfractionated and low-molecular-weight heparin.

[‡] Using the National Coordinating Council for Medication Error Reporting and Prevention (NCC MERP) *Index for Categorizing Medication Errors*.

Table 3. Number of Harmful Heparin Reports by Reporting Program and Node*

	Reports E-I	Reports E-I with Nodes	Prescribing	Transcribing	Dispensing	Administering	Monitoring
PA-PSRS	34	34	7 (20.6%)	1 (2.9%)	4 (11.8%)	21 (61.8%)	1 (2.9%)
MEDMARX	179	178 [†]	32 (18.0%)	25 (14.0%)	14 (7.9%)	97 (54.5%)	10 (5.6%)
PSN	62	47 [†]	11 (23.4%)	4 (8.5%)	2 (4.3%)	26 (54.2%)	4 (8.5%)
Total	275	259	50 (19.3%)	30 (11.6%)	20 (7.8%)	144 (55.6%)	15 (5.8%)

* PA-PSRS, Pennsylvania Patient Safety Reporting System; PSN, Patient Safety Net (United Health System Consortium).

[†] Reports do not add up because reports in which the node could not be determined have been omitted.

which the error actually occurred with the origination of the error. Hence, these findings contradict the previous statements on the node of the medication use process, which show that only 7.8% of the harmful heparin reports originated in the dispensing mode. In addition, those events attributed to the prescribing node could have occurred in a variety of locations in an organization and could skew the care areas selected in these reports.

SELECTED ERROR DESCRIPTIONS CONTAINED IN REPORTS

Determining and comparing the possible reasons why harmful events occur with the use of heparin across the three reporting systems was difficult. First, although the questions asked of reporters were often similar (for example, type of event, node, harm score) across the programs, the choices for causes and/or contributing factors were not. In addition, some of the reporting programs do not require these questions to be answered on all events. In the analysts' experience, reviewers can identify causes and contributing factors in the narratives even when they were not selected by the individual submitting the report. Therefore, each error that was categorized as meeting the NCC MERP Index of Category E through I was individually

reviewed. The intent of the review was to determine the node where the error originated and to determine, on the basis of the information provided and the authors' experience in reviewing event narratives, the proximal causes and contributing factors that may have contributed to the error. ISMP's Key Elements of the Medication Use System™ (Table 4, page 200) were used to categorize any possible causes (factors that directly lead to an error) or contributing factors (influences that affect the occurrence of medication errors),²¹ in each node for all reports that contained an adequate description of the error. The description of the event as well as other data fields available in the report were used to clarify, if possible, the breakdowns that may have occurred in the medication use process.

Prescribing Node Errors. Analysis of the 50 reports involving harm originating in the prescribing node included breakdowns in the key elements of patient information ($n = 19$), drug information ($n = 5$), and communication of drug information ($n = 11$). There was insufficient information in 15 reports to identify readily the key elements associated with the errors.

Of the 19 reports involving breakdowns in patient information, the most frequently identified breakdowns included missing or unused information regarding comorbid conditions/diagnosis (45%), drug allergies (25%), laboratory results

(10%), weight (10%), and medication profiles (5%).

Among errors involving low-molecular-weight heparins, failure to address a patient's renal function was the leading factor (8 out of 9) that was not taken into consideration for serious prescribing events. This group included two reports of deaths. A paraphrased description from one such report follows:

Patient with chronic renal failure presented with chest pain and was started on enoxaparin 30 mg every 12 hours, which was then increased to 60 mg every 12 hours. Patient underwent a cardiac catheterization and proceeded to bleed from the groin during night. The patient's hemoglobin was 11.6 on admission but decreased to 9.6 in 4 hours, then to 2.1 upon time of death.

Another error description cited a patient with a past history of heparin-induced thrombocytopenia (HIT) that was not considered when heparin was prescribed:

The patient was initially admitted and treated with heparin 5,000 units subcutaneously every 8 hours for venous thromboembolism (VTE) prophylaxis. His platelet count decreased over time and his PF4 antibody was positive. His HIT reaction was noted multiple times in his handwritten medical record and in electronic format. On transfer to our skilled nursing unit, he was restarted on heparin 5,000 units subcutaneously twice daily. The patient was walking with a physical therapist when he suddenly collapsed. He was cyanotic with oxygen saturation of 83%. He then regained consciousness and complained of chest pain.

There was one reported death due to orders written simply as "resume all meds":

A patient with a stent placement had aspirin, Lovenox, and Plavix placed "on hold" prior to surgery for an amputation of her right third toe. Following surgery, the physician wrote, "resume all previous orders," which did not include the patient's Plavix, Lovenox, and aspirin. The patient expired several days later, with two of three of her coronary arteries with stents being 100% occluded.²²

Administering Node Errors. The most commonly cited node in which medication errors involving heparin originated was administration (144 reports). Although three times as many errors were reported as originating in this node, the one reported death did not conclusively link the omission of one heparin dose to the patient's death.

Some 42.5% of the reports in this node did not clearly detail the causes or contributing factors of the error. Of the remaining 83 reports, the misuse of devices (for example, infusion pumps, intravenous lines) was the leading cause of errors (29.1%). The leading cause of errors with infusion devices was

due to errors in programming the device. Five reports involved a 10-fold overdose, suggesting omission or misplacement of a decimal point when programming. Double-key bounce errors may have led to two of these events, such as the following:

The rate of infusion was increased to 22 mL/hr but the pump was set at 222 mL/hr according to report. Heparin was turned off 15 minutes later due to bleeding from the patient's femoral site.

Discussion

The number of reports involving heparin collected during a one-year study period and the proportion of heparin-related reports involving harm validate efforts to focus on this high-alert medication for purposes of patient safety improvement. Although the volume of reports does not equate with the true frequency of adverse events in clinical practice, the fact that heparin was associated with 3.6% of all reported medication errors justifies placing a high priority on heparin-related errors.

We did not perform detailed statistical analysis to ascertain frequency of occurrence. Because of the nature of the data, statistical tests on frequencies, rates, or patterns can be misleading if one presumes that the frequency of reporting is closely related to the frequency of occurrence. Therefore, statistical analysis of voluntary adverse event reports should be done with caution.²³ These data are more appropriately used for hypothesis generation than hypothesis testing. Compiling aggregate data from several patient safety reporting programs may add additional support to what is known, but additional learning on the origination and causes of errors can be obtained only if details in the description of the error are provided.

People involved in the operation of reporting systems believe that it is more important to have good information on fewer cases than poor information on many cases. The perceived value of reports (in any type of reporting system) lies in the narrative that describes the event and the circumstances under which it occurred. Inadequate information provides no benefit to the reporter or the health system.²⁴

IMPLICATIONS FOR HEALTH CARE ORGANIZATIONS

The most commonly cited areas for breakdowns in the medication use process, identified in each of the three reporting systems, were administering and prescribing, which together accounted for 75% of reports. Health care organizations may wish to focus their review of heparin safety on these respective nodes.

In their landmark article on systems analysis of adverse drug events, Leape et al.²⁵ defined broad categories, or domains, where the underlying problems that result in medication errors

may be found. ISMP expanded on those domains in what is referred to as ISMP's Key Elements of the Medication Use Process™ (Table 4, right). These 10 elements were used to help categorize possible causes or contributing factors contained in the error report descriptions from all three programs. The system breakdowns most frequently cited in report descriptions were inadequate patient information being obtained, shared, or used; inadequate communication of drug information to those who need it; and errors with the use of devices (for example, intravenous infusion pumps). This specific type of information was not available as a choice for direct cause or contributing factor in any of the reporting programs, thus demonstrating the type of information that can be gleaned from a individual review of narratives which could not be provided by simply filling out a form or through statistical analysis.

The most frequently cited causes of errors in administration were related to errors in programming infusion pumps. Health care organizations can prevent such errors by standardizing infusion pump models, choosing "smart pumps" and programming dose limits into the pump's library with alerts and hard stops for unsafe doses, and requiring an independent double-check of pump programming against the medication administration record before activating the pump during medication administration of selected high-alert medications.

The most frequently cited causes of errors in prescribing were related to breakdowns in communicating patient information. Organizations should consider standardizing the location of critical patient information needed when prescribing heparin by using standard protocols for ordering heparin products as well as standard order sets or preprinted orders that include prompts for patient information such as allergies; patients' reactions, diagnoses, and comorbid conditions; and laboratory values.²³ Computerized prescriber order entry (CPOE) and electronic medical records, although still out of reach for many organizations, may also reduce the occurrence of errors in the prescribing node as long as vital patient information is required and organizations use standard protocols in these systems.

IMPLICATIONS FOR REPORTING PROGRAMS

All three reporting programs studied collect reports on near misses and events that reach the patient but do not cause harm. If one looks solely at harmful events and fails to examine near misses (also known as "close calls")—whether in a single hospital or in a large population-scale reporting program—the mental model one develops of the hazards of the clinical process under study would be considerably incomplete. Many state reporting programs have standardized according to the

Table 4. Institute for Safe Medication Practices (ISMP)'s Key Elements of the Medication Use System™

Patient information: Patient's pertinent demographic and clinical information including age, height, weight, diagnosis, comorbid conditions, lab values, and medications.

Drug information: Information that is accessible and up-to-date through a multitude of sources including drug references as well as organization's formularies, protocols, and dosing guidelines.

Communication of drug information: Methods of communicating drug orders including handwritten orders, verbal or telephone orders, faxed orders, and the use of dangerous abbreviations and dose designations.

Drug labeling, packaging and nomenclature: Includes drug names that look or sound-alike, organization- and manufacturer-ambiguous drug labeling and packaging, and unlabeled medication containers.

Drug standardization, storage, and standardization: Access to high-alert drugs and hazardous chemicals, storage of drug and standardization of drugs, drug concentrations, and limiting the dose concentration of drugs available in patient care areas.

Drug device acquisition, use, and monitoring: The procurement, maintenance, use, and standardization of devices used to prepare and deliver medications.

Environmental factors: Environmental factors that contribute to medication errors include poor lighting, noise, interruptions, poor work flow, and a significant work load.

Competency and staff education: Staff education on new medications, high-alert medications, medication errors that have occurred, protocols, and policies and procedures related to medication use.

Patient education: Patients are educated about the medications they are receiving and how to protect themselves from errors.

Quality processes and risk management: A nonpunitive, systems-based approach to error reduction is in place and supported, practitioners are stimulated to detect and report errors, and interdisciplinary teams regularly analyze errors that have occurred.

Adapted from a variety of sources, including Institute for Safe Medication Practices: *Frequently Asked Questions*. http://www.ismp.org/faq.asp#Question_3 (last accessed Mar. 17, 2010), and Cohen M.R.: *Causes of medication errors*. In Cohen M.R. (ed.): *Medication Errors*, 2nd ed. Washington, DC: American Pharmaceutical Association, 2007, p. 56.

National Quality Forum's Serious Reportable Event list to identify reportable events.²⁶ If the three programs studied here had followed this list, we might have reviewed only 10 reports about medication errors involving heparin (those involving permanent harm or death) instead of more than 10,000. Such a limited view would have provided scant information from which to generalize recommendations that would apply across orga-

nizations. At the level of the individual organization, collecting information on only the most harmful events provides few opportunities to discover when attempts to eradicate identified problems have not been successful. We believe this underscores the importance of collecting information on near misses at the local, regional, and national levels. Although collecting reports on the NQF Serious Reportable Events may be suitable for an accountability system, it is inadequate for a learning system.

During the review of individual reports in this project, we noticed that many adverse event reports involving any clinical process usually provided limited information and insight. This limitation may be due to a variety of factors, including the frontline reporter's recollection, understanding not only of what happened but also of the causes and contributing factors that lead to errors, judgment about what facts are important to relate, and communication skills, and the time the reporter spent in writing the report. Although aggregating many reports on the same clinical process and reviewing the description of the event may hamper effective analysis and follow-up, it enables one to arrive at a rich and more complete understanding of the weak links in the process and all the causes and contributors that lead to adverse events.

IMPLICATIONS FOR THE NATIONAL NETWORK OF PATIENT SAFETY DATABASES

This study represents the first attempt by these three large reporting systems to combine data on a single clinical process. The challenges that we encountered bear on the Network of Patient Safety Databases.⁹ The consistent patterns evident in the reports across the three reporting systems, such as the percentage of all medication errors that involved heparin, suggest two tentative conclusions that could be confirmed by further research. First, it is a form of validation that these systems each independently observed similar patterns in the reports studied. Second, it suggests that reporting programs, at least for common events such as medication errors, may reach a point of diminishing returns in which aggregating more reports of a certain type yields no additional insight once a large volume of similar events from many institutions is captured and analyzed. This would be less of an issue for rarer events (such as operating room fires or wrong-site surgeries), where even regional or national programs might have few reports. This would not negate the value of combining reports among programs of more limited scope. Nor would it negate the value of continuously collecting such reports locally where their use in "signal detection" can identify problems that have not been resolved or "fixes" that have created new problems.

Notably, much of our analysis relied on our interpretation of data and context appearing in the free-text narrative or "event description" field. Even the most robust classification schemes are limited by the user's training and skill, and the average frontline clinician who is closest to the event is not a frequent user of these classifications. As we discovered in our study, this would make it necessary for the analyst to annotate cases, adding to the frontline reporter's characterization of the event—and, in some cases, changing the reporter's classifications when they are inconsistent with other information in the report. The significance of the narrative, therefore, cannot be overstated.

LIMITATIONS

Although the sample was drawn from three large patient safety reporting programs, it represents a small percentage of the heparin-related errors that occur in clinical practice. Because of the retrospective nature of the study and the large number of reports involved, we were unable to follow up with each facility to obtain further information on individual reports.

Direct comparisons between the reporter's data entry choices among all three programs posed challenges. The PSN and PA-PSRS programs' reporting mechanisms were more similar in nature, with similar questions and choices for answers, while the MEDMARX program had some significant differences. Many fields or questions were similar and "lined up" between the reporting programs, such as date the event occurred, node, and name of the drug, which allowed for statistical comparisons. However, this did not mean the reporters could choose similar responses. For example, when choosing the node of the event, MEDMARX asked reporters to select only one, while PSN and PA-PSRS asked to "select all that apply." When selecting the type of medication error (for example, wrong drug, wrong rate), MEDMARX allows users to select multiple responses, whereas PA-PSRS and PSN users could only select one type of event.

In addition, although all three programs featured many similar selections (for example, wrong-dose errors), the PA-PSRS and PSN systems allow users to select either "wrong dose/over dosage" or "wrong dose/under dosage"; MEDMARX only asks for "improper dose/quantity." Sometimes, a field would be mandatory in one reporting system but not others. For example, "patient age" and "gender" are required fields in PA-PSRS and PSN but not MEDMARX. A portion (33%) of the MEDMARX reports nonetheless featured data for those fields, which the reporters chose to voluntarily provide.

Several data fields did not completely align in the three programs, making some comparisons difficult. For example, each reporting program allowed reporters to select the care area where the event took place, yet the actual choices differed across the reporting programs. The MEDMARX program provides separate questions between causes of medication errors and possible contributing factors, whereas PSN and PA-PSRS only ask reporters for “system factors contributing to medication error,” which are broken down by the nodes in the medication use process. Therefore, doing a true statistical comparison between all three programs would have led to misleading and possibly inaccurate conclusions.

This project was based on information provided in each medication error report and review of each report by individuals from each reporting program. The information provided in reports was often inadequate, especially “how” and “why” the event occurred. More than 30% of the descriptions in reports involving harm did not contain adequate information to determine causes or contributing factors.

Although the individuals reviewing the reports had varied backgrounds (pharmacist, nurse, and physician), potentially influencing their assessments, all reviewers were familiar with reviewing error reports for their respective programs. It is possible that some reports may have overlapped if organizations were using multiple reporting programs. For example, the State of Pennsylvania mandates the use of PA-PSRS, and some organizations in the state were already using MEDMARX or PSN, so that some reports may have been entered into two systems. **1**

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References

1. Institute of Medicine: *To Err Is Human: Building a Safer Health System*. Washington, DC: National Academy Press, 2000.
2. Dovey S.M., Phillips R.L.: What should we report to medical error reporting systems? *Qual Saf Health Care* 13:322–323, Oct. 2004.
3. Furukawa H., et al.: Voluntary medication error reporting program in a Japanese national university hospital. *Ann Pharmacother* 37:1716–1722, Nov. 2003.
4. Leape L.L.: Reporting of adverse events. *N Engl J Med* 347:1633–1638, Nov. 14, 2002.
5. Murphy J.G., et al.: Journal reporting of medical errors: The wisdom of Solomon, the bravery of Achilles, and the foolishness of Pan. *Chest* 131:890–896, Mar. 2007.
6. Schulman K.A., Kim J.J.: Medical errors: How the US Government is addressing the problem. *Current Controlled Trials in Cardiovascular Medicine* 1(1):35–37, 2000.
7. Suresh G., et al.: Voluntary anonymous reporting of medical errors for neonatal intensive care. *Pediatrics* 113:1609–1618, Jun. 2004.
8. Rosenthal J., Takach-Booth M.: Maximizing the Use of State Adverse Event Data to Improve Patient Safety. Oct. 2005. <http://www.nashp.org/node/826> (last accessed Mar. 16, 2010).
9. U.S. Agency for Healthcare Research and Quality (AHRQ): *Network of Patient Safety Databases*. <http://www.pso.ahrq.gov/npsd/npsd.htm> (last accessed Mar. 16, 2010).
10. Hicks R.W., et al.: *MEDMARX Data Report: A Chartbook of Medication Errors Findings from the Perioperative Settings from 1998–2005*. 2006. <http://www.usp.org/hqi/patientSafety/medmarx/> (last accessed Mar. 16, 2010).
11. Hicks R.W., et al.: *MEDMARXSM 5th anniversary Data Report: A Chartbook of 2003 Findings and Trends 1999–2003*. 2004. <http://www.usp.org/hqi/patientSafety/medmarx/> (last accessed Mar. 16, 2010).
12. Nicolai C.S., et al.: Unfractionated heparin: Focus on a high-alert drug. *Pharmacotherapy* 24(8 pt. 2):146S–155S, Aug. 2004.
13. Santell J.P., et al.: *MEDMARX Data Report: A Chartbook of 2000–2004 Findings from Intensive Care Units and Radiological Services*. 2005. <http://www.usp.org/hqi/patientSafety/medmarx/> (last accessed Mar. 16, 2010).
14. Institute for Safe Medication Practices: *ISMP's List of High-Alert Medications*. <http://www.ismp.org/Tools/highalertmedications.pdf> (last accessed Mar. 16, 2010).
15. The Joint Commission: *Facts About the 2010 National Patient Safety Goals*. http://www.jointcommission.org/NR/rdonlyres/868C9E07-037F-433D-8858-0D5FAA4322F2/0/RevisedChapter_HAP_NPSG_20090924.pdf (last accessed Mar. 16, 2010).
16. The Joint Commission: Issue 41: Preventing errors relating to commonly used anticoagulants. *Sentinel Event Alert*, Sep. 24, 2008: http://www.jointcommission.org/SentinelEvents/SentinelEventAlert/sea_41.htm (last accessed Mar. 16, 2010).
17. Federico F.: Preventing harm from high-alert medications. *Jt Comm J Qual Patient Saf* 33:537–542, Sep. 2007.
18. Patient Safety Authority: *PA-PSRS (Pennsylvania Patient Safety Reporting System)*. <http://patientsafetyauthority.org/PA-PSRS/Pages/PAPSRs.aspx> (last accessed Mar. 16, 2010).
19. National Coordinating Council for Medication Error Reporting and Prevention: *NCC MERP Index for Categorizing Medication Errors*. <http://www.nccmerp.org/medErrorCatIndex.html> (last accessed Mar. 16, 2010).
20. Forrey R.A., et al.: Interrater agreement with a standard scheme for classifying medication errors. *Am J Health Syst Pharm* 64:175–181, Jan. 15, 2007.
21. Cohen M.R. (ed.): *Medication Errors*, 2nd ed. Washington, DC: American Pharmaceutical Association, 2007, p. 56.
22. Santell J.P.: Reconciliation failures lead to medication errors. *Jt Comm J Qual Patient Saf* 32:225–229, Apr. 2006.
23. Institute for Safe Medication Practices: High-alert medication feature: Anticoagulant safety takes center stage in 2007. *ISMP Med Saf Alert! Acute Care*, Jan. 11, 2007. <http://www.ismp.org/Newsletters/acute/articles/20070111.asp?ptr=y> (last accessed Mar. 16, 2010).
24. Zhan C., et al.: How useful are voluntary medication error reports? The case of warfarin-related medication errors. *Jt Comm J Qual Patient Saf* 34:36–44, Jan. 2008.
25. Leape L.L., et al.: Systems analysis of adverse drug events. *JAMA* 274:35–43, Jul. 5, 1995.
26. National Quality Forum: *Serious Reportable Events (Fact Sheet)*. Jan. 2010. http://www.qualityforum.org/Publications/2008/10/Serious_Reportable_Events.aspx (last accessed Mar. 16, 2010).